IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., and NOVOPHARM, LTD., Counterclaim Plaintiffs, v. ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTÉ, and LABORATOIRES FOURNIER S.A., Counterclaim Defendants.	C.A. No. 02-1512 (SLR) CONSOLIDATED
IMPAX LABORATORIES, INC., Counterclaim Plaintiff, v. ABBOTT LABORATORIES, FOURNIER INDUSTRIE ET SANTÉ, and LABORATOIRES FOURNIER S.A., Counterclaim Defendants.	C.A. No. 03-120 (SLR) CONSOLIDATED
IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	C.A. No. 05-340 (SLR) CONSOLIDATED
IN RE TRICOR INDIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	C.A. No. 05-360 (SLR) CONSOLIDATED

DEFENDANTS' REPLY BRIEF IN SUPPORT OF MOTION FOR LEAVE TO FILE A MOTION FOR SUMMARY JUDGMENT ON ANTITRUST INJURY

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Mary B. Graham (#2256)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
mgraham@mnat.com
jparrett@mnat.com

OF COUNSEL:

William F. Cavanaugh, Jr.
Thomas W. Pippert
Chad J. Peterman
Alexis Deise
PATTERSON, BELKNAP, WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
(212) 336-2000

Attorneys for Defendant Abbott Laboratories

RICHARDS, LAYTON & FINGER, P.A.
Frederick L. Cottrell, III (#2555)
Anne Shea Gaza (#4093)
One Rodney Square
P.O. Box 551
Wilmington, DE 19899
(302) 651-7700
cottrell@rlf.com
gaza@rlf.com

OF COUNSEL:

William Baer
James Cooper
Anne P. Davis
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, DC 20004
(202) 942-5000

Timothy C. Bickham
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, N.W.
Washington, DC 20036-1795
(202) 429-5517

Attorneys for Fournier Industrie Et Santé and Laboratoires Fournier, S.A.

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INTRODUCTION

To prevent Defendants' motion for summary judgment on antitrust injury from being heard, Plaintiffs stage a multi-faceted and entirely unsupported attack. They misquote and mischaracterize Judge Jordan's opinion to convince the Court that the issues the proposed motion would present have already been decided at the motion to dismiss stage. They suggest, without basis, that Defendants have already conceded that antitrust injury exists. They even threaten to burden the Court with voluminous (but irrelevant) filings and claim that the proposed motion will derail the schedule in this case.

Plaintiffs' efforts are unavailing. As discussed below, Judge Jordan did not consider or rule upon the antitrust injury issue Defendants' proposed motion would present. The absence of antitrust injury can be decided as a matter of law, as the only material facts have been demonstrated in discovery to be undisputed. Moreover, rather than derail the schedule set by the Court in this case, Defendants' proposed motion promotes efficiency by providing the Court with an appropriate tool for narrowing or disposing of Plaintiffs' claims.

Plaintiffs' fear that the Court might entertain Defendants' proposed motion for summary judgment on antitrust injury is understandable. The proposed motion lays bare that *Plaintiffs are unable to prove an essential element of their antitrust claims.*

ARGUMENT

I. JUDGE JORDAN DID NOT CONSIDER THE ANTITRUST INJURY ISSUE DEFENDANTS' MOTION WOULD PRESENT

The only argument made by Defendants at the motion to dismiss stage with respect to market foreclosure or "consumer choice" – and the only such issue upon which Judge Jordan ruled – was that because Plaintiffs and other competitors were free to enter the market with branded fenofibrate products, they could not establish "anticompetitive effect" or "harm to

competition," which is an essential element of *antitrust liability* under their *Sherman Act* claims.[1] Here, Defendants seek to brief the separate and distinct issue of whether, in light of the facts revealed in discovery about the availability of consumer choice, Plaintiffs can meet the required *antitrust injury* element of their claims for damages under Section 4 of the Clayton Act.

As Plaintiffs themselves recognize, this is a fundamentally different argument; it focuses not on the anticompetitive harm alleged, but on the *relationship* between the plaintiff's injury and the anticompetitive harm caused by [defendants' alleged] violation."[2] The Third Circuit has explicitly held that a court needs to distinguish "the antitrust injury that is required for a plaintiff to have standing to bring an antitrust claim [under Section 4] from the anticompetitive market effect element of a claim under Section 1." *Angelico v. Leheigh Valley Hosp., Inc.*, 184 F.3d 268, 273 (3d Cir. 1999). Plaintiffs' focus on Judge Jordan's discussion of market foreclosure and its relation to *anticompetitive harm* misses the point.[3]

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1 *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 420-23 (D. Del. 2006) (discussing "Foreclosure from the Market" under the section heading "Antitrust Liability for Product Formulation Changes"); *see also* Direct and Indirect Purchaser Pls.' Opp'n to Mot. For Leave To File a Mot. For Summ. J. on Antitrust Injury ("Purchaser Pls.' Opp'n") (C.A. 05-340, D.I. 393; C.A. 05-360, D.I. 383) at 3, 5 (noting that Judge Jordan found "that competitors need not be completely foreclosed . . . in order to trigger *antitrust liability*" and acknowledging that the issue Judge Jordan ruled on was "whether [Defendants'] conduct constitutes a violation of the antitrust laws." (emphasis added)); Teva and Impax's Joint Opp'n to Defs.' Mot. For Permission to File a Mot. for Summ. J. on Antitrust Injury ("Manufacturer Pls.' Opp'n") (C.A. 02-1512, D.I. 601; C.A. 03-120, D.I. 507) at 4 (describing Judge Jordan's "analysis of the anticompetitive effect" of Defendants' conduct). Of course, Judge Jordan's findings regarding consumer choice were, at the motion to dismiss stage, based on Plaintiffs' allegations, something Plaintiffs conveniently ignore in their discussion of his decision. *See Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d at 420-23.

2 Purchaser Pls.' Opp'n at 5 (citing *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 342 (1990)).

3 Purchaser Pls.' Opp'n at 3-4; Manufacturer Pls.' Opp'n at 4-5. Similarly, the "settled law" cited by Manufacturer Plaintiffs, all of which involves Sherman Act elements of *liability* – not Clayton Act antitrust injury, is irrelevant to the issues Defendants would present in the proposed motion for summary judgment. *See United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191-93 (3d Cir. 2005) (discussing "anti-competitive effects" as

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It is clear on the face of Judge Jordan's opinion that Defendants did not brief, and the Court did not consider, whether the undisputed fact that other fenofibrate products were able to enter the market precludes a finding of antitrust injury here. Indeed, the suggestion by Purchaser Plaintiffs that Judge Jordan had previously ruled on whether Defendants' introduction of new products and removal of old products from the market resulted in antitrust injury misstates the record. Purchaser Plaintiffs contend that "Judge Jordan also ruled that the injury resulting from Defendants' alleged scheme to suppress generic competition constitutes antitrust injury." That is simply incorrect. As Judge Jordan explicitly noted, Defendants limited their arguments on antitrust injury at the motion to dismiss stage to Plaintiffs' *Walker Process* and sham litigation claims, and did not argue on their motion to dismiss "that Plaintiffs have failed to allege antitrust injury for their overall scheme claims taken as a whole."[4] Far from conceding that their conduct, taken as a whole, resulted in antitrust injury (as Plaintiffs inexplicably suggest), Defendants made the determination that their antitrust injury arguments as to the product introductions and withdrawals would be better presented on summary judgment, supported by a full discovery record. There is nothing inappropriate about this approach, and the resulting discovery record in fact confirms that the injury Plaintiffs complain of does not constitute "antitrust injury."

Finally, Plaintiffs' mantra that Judge Jordan's ruling on the motion to dismiss is the "law of the case" should not preclude this Court from examining on summary judgment

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an element of Sherman Act Section 2 liability); *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001) (same).

[4] *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d at 430-31 ("Since the claim depends on proof of the anticompetitive effect of the conduct as a whole, the question of antitrust injury should also be based on that conduct as a whole.").

every element of Plaintiffs' novel antitrust theory. It is well settled in the Third Circuit that the "law of the case" doctrine does not restrict a court's power, but rather governs its exercise of discretion. *In re City of Philadelphia Litig.*, 158 F.3d 711, 718 (3d Cir. 1998). In particular, a successor court is free to consider on a motion for summary judgment issues addressed by the predecessor court on a motion to dismiss. *See, e.g.*, *Carmichael Arbors Assocs. v. United States*, 789 F. Supp. 683, 687 (W.D. Pa. 1992) (successor court is "free to reconsider" on summary judgment the predecessor's pronouncements regarding the constitutionality of a statute); *Lasky v. Am. Broad. Cos.*, 631 F. Supp. 962, 964 (S.D.N.Y. 1986) (on summary judgment successor judge is not bound by predecessor's decision on motion to dismiss and "this court is free to ignore the previous ruling."). Defendants propose here to present an issue not considered by Judge Jordan on the motion to dismiss, but the limited scope of Defendants' proposed motion should not be read to suggest that Defendants agree with Judge Jordan's finding that their product introductions and discontinuances constitute anticompetitive conduct to which a rule of reason analysis should be applied --they do not. Nor do Defendants believe that this Court is bound by Judge Jordan's decision on these issues. Defendants would be prepared to address these issues in further detail if the Court believed that doing so would be helpful.

II. PLAINTIFFS' ALLEGED "INJURY" FLOWS FROM THE GENERIC SUBSTITUTION LAWS, WHICH PREVENT AUTOMATIC SUBSTITUTION OF TEVA AND IMPAX'S FENOFIBRATE PRODUCTS FOR DEFENDANTS' NEW PRODUCTS

Defendants will demonstrate in their proposed motion that, in the context of an *antitrust injury* inquiry, it is simply not enough for Plaintiffs to show that Teva and Impax's preferred means of distribution was foreclosed while other distribution options remained. Where, as here, competitors, including Teva and Impax, were able to enter the market (and freely sell and promote their products) and Plaintiffs' claimed "injury" was simply a result of state

regulatory restrictions on the manner in which those competitors could distribute their products, no antitrust injury can be proven. *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998); *In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 791 (8th Cir. 2006).[5]

Defendants' introduction of a new Tricor formulation and withdrawal of the existing formulation did not prevent Teva, Impax and a number of other competitors from entering the market with fenofibrate products. Every physician in the United States had the ability to prescribe the fenofibrate formulation introduced by Teva and others. And these competitors had every opportunity to convince physicians to prescribe their competing fenofibrate products. Instead, Plaintiffs complain that the means of distributing these fenofibrate products preferred by Teva and Impax (that is, free-riding on TriCor's marketing through automatic generic substitution) was foreclosed and that all Plaintiffs were injured thereby. *See* Manufacturer Pls.' Opp'n at 6; Purchaser Pls.' Opp'n at 2 (acknowledging that Purchaser Plaintiffs' injury arises out of their inability to have generic fenofibrate products automatically substituted for TriCor prescriptions).

But that "injury" *does not flow from Defendants' conduct*. It is the result of limitations built into state prescription drug substitution laws that prevent Manufacturer Plaintiffs from having their fenofibrate products substituted for Defendants' *new* formulations. The core allegation of Plaintiffs' entire case, after all, is that Manufacturer Plaintiffs' fenofibrate products

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[5] Nothing in Judge Jordan's ruling suggests otherwise. In fact, the only instance in which Judge Jordan affirmatively held that any Plaintiff had adequately alleged antitrust injury was in the context of Teva's separate *Walker Process* claim, where Teva alleged *total exclusion* from the market during the pendency of the Tablet Litigation. Of course, a finding of antitrust injury on Teva's *Walker Process* claim presupposes antitrust liability on that claim, and, as set forth in Defendants' Motion for Summary Judgment on the Claims of "Sham Litigation" and *Walker Process* Violations, filed May 5, 2008 (C.A. 02-1512, D.I. 606; C.A. 03-120, D.I. 510; C.A. 05-340, D.I. 395; C.A. 360, D.I. 389), Plaintiffs can make no such showing of antitrust liability.

are therapeutic equals to Defendants' new TriCor products. The problem is that the substitution laws do not agree. Because the crux of Plaintiffs' complaints is that the allegedly therapeutically equivalent (but non AB-rated) generic fenofibrate products are being treated unfairly under the automatic substitution laws, Plaintiffs cannot demonstrate antitrust injury and their claims are subject to dismissal on summary judgment.

As Defendants demonstrated in their opening brief, the recent decision in *Walgreen Co. v. AstraZeneca Pharmaceuticals L.P.*, 534 F. Supp. 2d 146 (D. D. C. 2008) (the "*Nexium*" case) confirms that where, as here, consumer choice is preserved, no antitrust injury results from the introduction of a new branded product and aggressive efforts by the manufacturer to convert prescriptions away from a "virtually identical" predecessor product. *Id.* at 152. To the extent that generic sales are depressed in that competitive environment, the lost sales are due to the regulatory framework under state laws that limit pharmacy substitution of generic drugs to prescriptions written for the brand drug identified by the generic manufacturer in its ANDA, and do not allow substitution of all "bioequivalent" products. There simply is no difference, in the context of antitrust injury, between conduct that involves shifting marketing resources to a new product so physicians stop prescribing the old product, and conduct that instead involves withdrawing the old product from the market after a new product introduction. In neither case is the claimed "injury" (depression of generic sales) a result of the anticompetitive conduct alleged. Any injury instead flows from the regulatory framework that prevents automatic substitution of the generic products for the new allegedly "therapeutically identical" products, and thus does not constitute "antitrust injury."

Nor does the fact that the *Nexium* court distinguished Judge Jordan's decision change the antitrust injury analysis, because the distinction was based on Judge Jordan's

acceptance, at the motion to dismiss stage, of Plaintiffs' allegations that choice among fenofibrate products had been eliminated. *Id*. at 151 ("The elimination of choice was a critical factor in [Judge Jordan's] decision to deny Abbott's motion to dismiss the complaint."). In their proposed motion, Defendants will introduce undisputed facts that choices abound for consumers of fenofibrate products.

In a half-hearted attempt to side-step the determination in *Nexium* that no antitrust injury flows from the type of circumstances present here, Purchaser Plaintiffs suggest that the *Nexium* court really didn't know what it was doing. Specifically, Purchaser Plaintiffs suggest that "while the *Nexium* opinion ostensibly discusses 'antitrust injury,' it does not address the concept of antitrust injury as defined by the Supreme Court." Purchaser Pls.' Opp'n at 5, n.1. They go on to argue that the court's holding on antitrust injury is simply a "restatement" of its determination that AstraZeneca's conduct was not exclusionary. *Id.* But Plaintiffs' argument is belied by the court's language, which makes clear that it was focused, in its alternative holding, not on whether "competition" had been injured, but on whether plaintiffs had "identified an antitrust injury *that they have suffered.*" *Nexium*, 534 F. Supp. 2d at 152 (noting in conclusion that "Plaintiffs have not pled facts that support a reasonable inference that they have been damaged by an antitrust injury, *or* that AstraZeneca engaged in exclusionary conduct prohibited by § 2 of the Sherman Act.") (emphasis added).

After the *Nexium* decision, and in light of the undisputed facts revealed in discovery, it is clear that Plaintiffs' claimed harm does not flow from Defendants' conduct and that no antitrust injury can be demonstrated in this case.[6] Defendants respectfully submit that the

[6] The other "generic suppression" cases cited by the Purchaser Plaintiffs do not alter the result here. Plaintiffs cite *In re Warfarin Sodium Antitrust Litigation*, 214 F.3d 295 (3d Cir. 2000) and *In re Cardizem CD Antitrust Litigation*, 332 F.3d 895 (6th Cir. 2003), for (Continued . . .)

Court should permit Defendants to present their antitrust injury arguments on summary judgment.

III. DEFENDANTS' PROPOSED MOTION INVOLVES LIMITED MATERIAL FACTS AND NEED NOT DERAIL THE SCHEDULE IN THIS CASE

Knowing that this Court has taken on an increased case load, Teva and Impax threaten to bury the Court with "voluminous factual information to support their contentions." Manufacturer Pls.' Opp'n at 1. But none of the facts they threaten to raise in opposition to the proposed motion bear on the issue of whether Plaintiffs suffered "antitrust injury."[7] Indeed, Plaintiffs' laundry list of "facts" go to, in their words, "assessing the *competitive effect* of Defendants' action in foreclosing generic substitution . . . ."[8] Thus, by their own admission, Teva and Impax would submit an irrelevant factual record on alleged "anticompetitive effect" under the Sherman Act – not on the antitrust injury aspect of Clayton Act § 4.[9]

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the proposition that paying higher prices as a result of generic suppression constitutes antitrust injury. Purchaser Pls.' Opp'n at 6. But as these Plaintiffs themselves acknowledge, it is not the nature of the harm but whether that harm *flows from* the alleged anticompetitive conduct that matters in an antitrust injury analysis. In neither of the cases cited did the plaintiffs' claimed injuries flow from regulatory restrictions on the way generic products are substituted, as they do here. Moreover, in *Warfarin* plaintiffs alleged that the defendant had engaged in unlawful conduct – making false accusations about the AB-rated generic of Coumadin. Here, Plaintiffs cannot allege that the introduction and discontinuance of Tricor formulations were unlawful acts. Plaintiffs' theory is that these otherwise lawful acts became unlawful by virtue of their effect – stripping Plaintiffs of their claimed entitlement to a *status quo* market in which Defendants' old formulations of TriCor continue to be manufactured and sold in perpetuity.

7 *Id.* at 6-7.

8 *Id.* at 6 (emphasis added).

9 Assessment of the competitive effects of Defendants' alleged actions does not inquire whether Plaintiffs have suffered "injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendant[s'] acts unlawful." *Atl. Richfield Co.v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990); *Angelico*, 184 F.3d at 273 (distinguishing "the antitrust injury that is required for a plaintiff to have standing to

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The *only* facts that are material to Defendants' proposed motion are that: (1) throughout the class period doctors, patients, purchasers, and third-party payors have had fenofibrate choices despite the alleged exclusionary conduct, and (2) state generic substitution laws do not allow automatic substitution of Teva's and Impax's products for the new TriCor products. Tellingly, *none* of the Plaintiffs claim in their opposition papers that there is a genuine dispute over these facts. The reality is that the facts material to Defendants' proposed motion on antitrust injury are simple, few, and undisputed. Under these circumstances, there is no basis for proceeding to trial, as Plaintiffs urge, without allowing Defendants to present arguments on summary judgment.

Plaintiffs argue that Defendants' request is a motion for reconsideration and will adversely impact the schedule in this case. Neither argument has merit. The Court explicitly noted at the April 3 status conference that it was insufficiently familiar with Judge Jordan's opinion to make a determination as to whether summary judgment motions on additional issues might be appropriate. The Court now has a full record of what Judge Jordan addressed, and what he did not. There is more than enough time for the parties to brief these issues and for the Court to consider the important arguments that Defendants propose to make in their motion for summary judgment on antitrust injury.

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bring an antitrust claim [under Clayton Act Section 4] from the *anticompetitive market effect* element of a claim under [Sherman Act] Section 1." (emphasis added)).

CONCLUSION

For the reasons set forth above, Defendants respectfully request that the Court grant Defendants' motion for leave to file a motion for summary judgment on antitrust injury.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ James W. Parrett, Jr.

Mary B. Graham (#2256)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
mgraham@mnat.com
jparrett@mnat.com

OF COUNSEL:

William F. Cavanaugh, Jr.
Thomas W. Pippert
Chad J. Peterman
Alexis Deise
PATTERSON, BELKNAP, WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036-6710
(212) 336-2000

Attorneys for Defendant Abbott Laboratories

RICHARDS, LAYTON & FINGER, P.A.

/s/ Anne Shea Gaza

Frederick L. Cottrell, III (#2555)
Anne Shea Gaza (#4093)
One Rodney Square
P.O. Box 551
Wilmington, DE 19899
(302) 651-7700
cottrell@rlf.com
gaza@rlf.com

OF COUNSEL:

William Baer
James Cooper
Anne P. Davis
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, DC 20004
(202) 942-5000

Timothy C. Bickham
STEPTOE & JOHNSON LLP
1330 Connecticut Avenue, N.W.
Washington, DC 20036-1795
(202) 429-5517

Attorneys for Fournier Industrie Et Santé and Laboratoires Fournier, S.A.

Dated: May 12, 2008
2325248

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 12, 2008, the foregoing was caused to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

In addition, the undersigned hereby certifies that true and correct copies of the foregoing were caused to be served via electronic mail on May 12, 2008 upon the following parties:

REPRESENTING DIRECT PURCHASER CLASS PLAINTIFFS (LOUISIANA WHOLESALE, ROCHESTER DRUG, MEIJER) (C.A. 05-340)	Jeffrey S. Goddess **jgoddess@rmgglaw.com** Bruce E. Gerstein **bgerstein@garwingerstein.com** Barry S. Taus **btaus@garwingerstein.com** Adam M. Steinfeld **asteinfeld@garwingerstein.com** Daniel Berger **danberger@bm.net** Eric L. Cramer **ecramer@bm.net** Peter Kohn **pkohn@bm.net** Linda P. Nussbaum **lnussbaum@kaplanfox.com** Stuart Des Roches **stuart@odrlaw.com**
REPRESENTING WALGREEN, ECKERD, KROGER, MAXI (C.A. 05-340)	Elizabeth M. McGeever **emmcgeever@prickett.com** Scott E. Perwin **sperwin@kennynachwalter.com**
REPRESENTING CVS, RITE AID (C.A. 05-340)	Elizabeth M. McGeever **emmcgeever@prickett.com** Joseph T. Lukens **jlukens@hangley.com** Steve D. Shadowen **sshadowen@hangley.com**

REPRESENTING AMERICAN SALES COMPANY INC. (C.A. 05-340)	Elizabeth M. McGeever **emmcgeever@prickett.com** Scott E. Perwin **sperwin@kennynachwalter.com**
REPRESENTING INDIRECT PURCHASER CLASS PLAINTIFFS (C.A. 05-360)	A. Zachary Naylor Pamela S. Tikellis Thomas M. Sobol Patrick E. Cafferty Jeffrey L. Kodroff Bernard J. Persky Mike Gottsch Brian Clobes Michael Tarringer Tim Fraser David Nalven Greg Matthews Christopher McDonald Kellie Safar Theodore M. Lieverman Pat Howard **tricor@chimicles.com**
REPRESENTING PACIFICARE (C.A. 05-360)	Jonathan L. Parshall **jonp@msllaw.com** William Christopher Carmody **bcarmody@susmangodfrey.com** John Turner **jturner@susmangodfrey.com** Shawn Rabin **srabin@susmangodfrey.com** Justin Nelson **jnelson@susmangodfrey.com** Ken Zylstra **zylstra@verizon.net** Mark Sandman **mms@rawlingsandassociates.com** Jeffrey Swann **js5@rawlingsandassociates.com**

REPRESENTING TEVA PHARMACEUTICALS (C.A. 02-1512)	Josy W. Ingersoll Karen E. Keller Bruce M. Gagala Christopher T. Holding Ken Cohen Elaine Blais **tricor@ycst.com**
REPRESENTING IMPAX LABORATORIES (C.A. 03-120)	Mary Matterer **mmatterer@morrisjames.com** Asim Bhansali **abhansali@kvn.com**
REPRESENTING FOURNIER (ALL CASES)	Frederick L. Cottrell, III Anne Shea Gaza Steven C. Sunshine Matthew P. Hendrickson Bradley J. Demuth Maggie DiMoscato Timothy C. Bickham **tricor@rlf.com**

/s/ James W. Parrett, Jr.

James W. Parrett, Jr. (#4292)

520842